A framework for the adoption of redistributed manufacturing strategies in pharmaceutical supply chains

Samuel Roscoe (s.roscoe@sussex.ac.uk)

Constantin Blome (c.blome@sussex.ac.uk)
School of Business, Management and Economics
University of Sussex
Brighton BN1 9SL
United Kingdom

Abstract

This paper explores the adoption of redistributed manufacturing strategies by UK pharmaceutical firms. A multiple case study of six firms is coupled with expert opinion from academics in the fields of innovation, life sciences, pharmaceuticals and additive manufacturing. A triangulated data collection strategy is used including twenty-five semi-structured interviews, eight focus groups and primary documentation. Drawing on adoption theory we identify the enablers of and barriers to the adoption of redistributed manufacturing strategies. The findings suggest that redistributed manufacturing will not replace existing supply chain configurations but instead complement them. Several potential niche applications for redistributed manufacturing are identified.

Keywords: Redistributed Manufacturing, Adoption Theory

Introduction

Increasingly complex and globally dispersed supply chains are creating significant risks for multinational firms. Pharmaceutical supply chains are particularly susceptible to the risk of disruption (Abdallah, 2013; Harrington and Najim, 2014). As pharmaceutical products are research and development intensive, complex to produce and heavily regulated, supply chains tend to be long, slow and expensive (Harrington and Najim, 2014). Moreover, demand shocks can be quite unpredictable, as in the event of an epidemic. Uncertainty combined with long replenishment lead times tends to mean pharmaceutical firms hold significant inventory at various points in the chain (Calabrese and Pissavini, 2011). Typically, inventory equates to 30 – 90% of annual demand, with anywhere between 4–24 weeks' worth of finished good stocks being held (Shah, 2004). Indeed, the top 25 pharmaceutical companies are said to hold inventory in the range of $100-150billion at any one point in time (Harrington and Srai, 2014).

Redistributed manufacturing (RDM) is one potential remedy to the risks inherent in global pharmaceutical supply chains. RDM utilizes recent advances in manufacturing technology as a proactive strategy for risk mitigation. Used as an umbrella term, redistributed manufacturing captures the quickly changing supply chain structures associated with new manufacturing technologies such as additive manufacturing (3D printing) and continuous manufacturing (Pearson et al., 2013). These technologies

represent a shift away from the centralised batch manufacturing model towards smaller scale, localised manufacture for local markets. RDM is said to improve responsiveness to demand due to more localised, on-demand production possibilities (Campbell et al., 2011). A shift from physical to digital designs reduces the need to transport finished parts and goods, instead placing emphasis on transporting raw materials and digitally sending designs to local production sites (ibid). The lessened reliance on transporting finished parts results in fewer nodes and reduced supply chain complexity (Birtchnell et al., 2013). Decreased complexity and improved responsiveness has profound consequences for managing supply chain risks as the probability and impact of disruptive events related to forecasting and inventory is significantly reduced (Petrovic et al., 2011).

One technology particularly suited to the redistributed manufacturing model is additive manufacturing. The ability to additive manufacture drugs for immediate use can combat the tendency of some drugs to degrade on storage (Kommanaboyina and Rhodes, 1999). Additive manufacture opens up the possibility of personalized medicine where individualized combinations of drugs could be produced, helping to ensure patient compliance (Içten et al., 2015). The technology can also create more porous pills allowing faster drug release, helpful in cases where oral delivery of pills is difficult (Sandler et al., 2011). Moreover, entirely new formulation types of molecular substrates with complex drug release profiles could be produced, presenting the possibility of treating many chronic conditions that are currently out of reach (Khaled et al., 2014).

Due to the potential benefits of redistributed manufacturing we attempt to answer the question: how can pharmaceutical firms adopt redistributed manufacturing strategies? To answer this question we draw on adoption theory to develop a theoretical framework for the adoption of redistributed manufacturing strategies. The next section reviews the literature pertinent to answering the research questions of interest. The third section presents the findings from multiple case studies in the U.K. pharmaceutical industry. The paper concludes by outlining the theoretical and managerial contribution of the paper.

Literature Review

In the 1990's, the construct of supply chain risk management (SCRM) emerged to help firm's manage the increasing complexity associated with the globalization of supply chains. SCRM is defined as "the management of supply chain risk through coordination or collaboration among the supply chain partners so as to ensure profitability and continuity" (Tang, 2006). Since its inception, SCRM scholars have identified many types of supply chain risks including forecast risks, intellectual property risks, inventory and systems risks, financial flow risks, delays and disruptions (Chopra and Sodhi, 2004; Tang and Musa, 2011). Innovation, particularly innovation on the part of suppliers, has been advanced as one means of addressing supply chain risks (Choi and Krause, 2006).

Innovation can be understood as "new combinations" of new or existing knowledge, resources, equipment and so on (Schumpeter, 1934 p. 65). The adoption of innovation has been an area much studied in the management literature (i.e. Frambach and Schillewaert, 2002; Rogers, 2003). According to Rogers (2003) an organizations' decision to adopt an innovation occurs over five stages. During the agenda setting stage an organization identifies problems which may create a perceived need for an innovation and the environment is scanned for innovations of potential value. During the second stage, an innovation is identified which can address a firm's problems and the fit between them is planned and designed (matching stage). In the third stage, the innovation is re-invented to address the perceived problems and organizational structures are altered to accommodate the innovation (restructuring and re-invention stage). The organization then clarifies the relationship between the innovation and the organization more clearly as the

innovation is put into regular use (clarification stage). Finally, the innovation loses its separate identity and becomes an element in the organizations ongoing activities (routinizing stage) (Rogers, 2003).

The perception of organizational decision makers affects their evaluation of and propensity to adopt an innovation (Frambach and Schillewaert, 2002). For an organization to be persuaded to adopt an innovation it must demonstrate a relative advantage to the incumbent technology (Anderson and Narus, 1990). Moreover, the innovation must be perceived as being compatible with the existing values and needs of potential adopters (Rogers, 2003). Other factors that influence the likelihood of adoption include complexity and whether a potential adopter can trial the innovation (ibid). The final factor is the ability to observe the results and benefits of the innovation. Of these factors, relative advantage and complexity are said to have the greatest impact on how quickly a new technology is adopted (ibid).

Research Method

We apply Rogers' (2003) innovation adoption stage model to understand the uptake of redistributed manufacturing strategies in the pharmaceutical industry. A multiple case study design is selected as it offers in-depth data gathering and analysis opportunities (Dyer and Wilkins, 1991). Moreover, a multiple case study design allows within and across case comparisons and is often consider more robust then single case designs (Yin, 2014). Data is gathered from six case companies, four of which are global leaders in the pharmaceutical sector and two smaller U.K. based firms. A comparison between large and small firms allows us to control for the effects of organizational size. In addition to the case companies, expert opinion is gathered from leading academics in the fields of innovation, additive manufacturing, life sciences and pharmaceuticals.

To improve the validity and reliability of the findings we used a triangulated data collection method (Yin, 2014) including twenty-five semi-structured interviews and eight focus groups which was then objectively verified using primary and secondary data sources. A snowball sampling technique was used to select each interviewee (Taylor and Bogdan, 1998). Data collection stopped when a point of theoretical saturation was reached (Eisennhardt, 1989). NVIVO 10 software was used to code the interview transcripts, focus group notes and company documentation. Using hierarchical coding, groups of similar codes were clustered together to produce themes which, in combination, provided a rich story about the case (Eisennhardt and Graebner, 2007).

Findings

The following section relates the research findings to Rogers' (2003) innovation adoption model. In so doing, several enablers of and barriers to the adoption of redistribution manufacturing innovations are identified.

Stage 1: Agenda Setting Stage

During the agenda setting stage an organization identifies problems which may create a perceived need for an innovation and the environment is scanned for innovations of potential value. The SCRM literature has identified several potential problems, or risks, associated with globalized supply chains. Additional risks, particular to the pharmaceutical industry, were identified during data collection (see Table 1). These risks include single sourcing arrangements where large multinational pharmaceutical firms are reliant upon one primary manufacturing supplier. In such an arrangement, pharmaceutical firms are oftentimes only a small proportion of the supplier's order book, creating an imbalance of power in favour of the supplier. Another significant challenge is overcoming

the regulatory challenges of switching suppliers. Suppliers have to adhere to Good Manufacturing Practices (GMP) and be certified by agencies such as the Food and Drug Administration, a process that may take several years. Finally, insufficient capacity was found to exist within the centralised distribution model used by multinational pharmaceutical firms. Lack of capacity restricted the ability to flexibly respond to demand spikes with companies often having to stop production of one product, to give priority to the production of an urgent drug (see Table 1).

Table 1: Problems identified during the agenda setting stage

Stage	Theme	Code	Quote from Interviewee
Agenda Setting Stage	Current problems faced by global pharma supply chains	Single-sourcing arrangements in primary manufacture	"There is a total imbalance of power. So we are locked in and suppliers know it too well. So we need to find new ways of ensuring that you will be perceived as a preferred customer by your most critical suppliers." "We have several hundred materials that only one company in the world produces, and there is no alternative. Those are impossible because they are registered, it's IP, you cannot even develop alternative suppliers to build up the same thing, And for those, the best risk mitigation is to be as friendly as possible and very close"
		Regulatory challenges associated with switching suppliers	"For critical suppliers we're talking about years. The cycle time is very long... if the extent of the change implies some clinical trials, forget about it, it can then be very costly and very long… it can take more than five years." "We're not in a position to just freely pick up and put down suppliers at the drop of a hat. It would need to be a fairly serious issue."
		Lack of production capacity which restricts ability to flexibly respond to fluctuations in demand	"So if you're already running 24/7 shifts and you've got a full order book, then the opportunity to reprioritise is limited. If you've been optimising your supply strategy, your buffers of product to enable you to turn something off for a period of time would also be impacted." "We've rationalised globally the number of sites we use a company. So I think if you look at it like that there's less net capacity than there was…with these capacity challenge these days, you do end up with stock outs, the problem is that we just don't have enough global capacity."

March (1981) asserts that innovation adoption by organizations is often driven less by problems than by solutions. Most organizations face a multitude of problems but possess knowledge of only a few innovations that offer solutions. If one begins with a solution, there is a good chance that the innovation will match some problem that is facing the firm. Consequently, most organizations continuously scan for innovations and match any promising innovation found with some relevant problem (March, 1981). A similar problem solving approach was apparent at each of the case companies, particularly in the instance of additive manufacturing. As one focus group participant explained: "3D Printing is like a solution looking for a problem." The conundrum faced by the case companies was how to suitably match the innovation to the right problem.

Stage 2: Matching Stage

During the matching stage an innovation is identified which can address a firm's problems and the fit between them is planned and designed. For a decision maker to be persuaded to adopt an innovation it must demonstrate a relative advantage to the incumbent technology (Rogers, 2003). In many industries, additive manufacturing is being looked upon as revolutionary technology that will replace current manufacturing processes. In aerospace, for example, additive manufacturing is seen as a technology that will replace current casting and forging processes (Gibson et al., 2014). Aerospace firms are interested in the technology's ability to print lighter weight parts, which reduces engine weight and therefore improves fuel usage, the most significant cost to airlines. Similarly, automotive firms see additive manufacturing as a technology that can reduce vehicle weight and offer more customized products for consumers (Manyika et al., 2013).

Despite the widespread adoption of additive manufacturing in aerospace and automotive, this study did not find the same rate of uptake in the pharmaceutical industry. More specifically, interviewees did not see additive manufacturing as a technology that would disrupt current manufacturing processes. Instead, it was suggested that additive manufacturing would act as a complementary innovation that functioned alongside current production technologies. This sentiment is captured in the following quote:

> "One of the challenges associated with introducing people to 3D printing is this preconceived idea that they'll use it to print something they already have. And usually though, that product has been manufactured with that manufacturing technology in mind. This is a different technology that uses a different way of forming things that has different advantages compared to other ways. So you have to really think about, what do you want out of your product and can 3D printing realise that?"

This quote suggests that, in the pharmaceutical industry at least, additive manufacturing is not likely to radically transform current manufacturing methods, certainly not in the near term. The questions then arises of whether additive manufacturing needs to demonstrate a relative advantage over incumbent technologies to be adopted. The quotes captured in Table 2 suggests this may not be the case.

Table 2: Ability to demonstrate a relative advantage to incumbent technology

Stage	Theme	Code	Quote from Interviewee
Matching Stage	Innovation's ability to demonstrate a relative advantage to incumbent technology	Does not need to demonstrate a relative advantage as not a replacement	"Many evangelists, if you like, in this industry say '3D printing is a substitute technology to others'. However, the more conservative approach is to say 'okay, they 3D printing technology will be some sort of complement to actual manufacturing lines"
			"My personal opinion would be that 3D printing will be just part of the spectrum of manufacturing technologies, so it will somehow be embedded within an existing supply chain."
			"There is a kind of, a myth that additive manufacturing, 3D printing, will replace all traditional manufacturing. And that is not likely to ever happen. It will be a complimentary technology that will enable you to do different things."

Here we find a slight difficulty with Rogers' (2003) innovation adoption model. He argues that to persuade organizational decision makers to adopt an innovation it must demonstrate a relative advantage over the incumbent technology. Yet, the findings suggest that additive manufacturing is not likely to act as a replacement, but instead as a complementary technology. Such a technology does not easily fit into Rogers' model. We are then left to explore other factors that may be inhibiting the rate of adoption. Table 3 suggests it is not the complexity of additive manufacturing but instead the lack of complexity in the control systems that monitoring product quality that is slowing the rate of adoption. An inability to verify the quality of manufactured products creates challenges in getting the process certified by regulators.

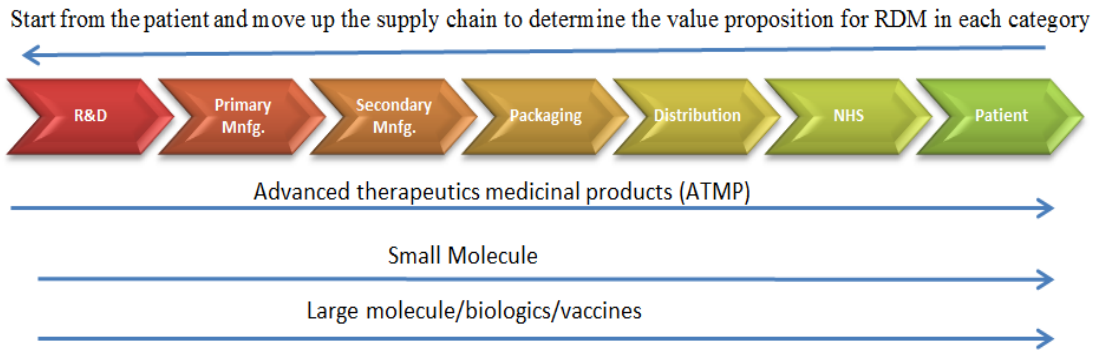
Table 3: Complexity and ease of use by potential innovation adopter

Stage	Theme	Code	Quote from Interviewee
Matching Stage	Complexity-ease of use by potential adopter	Lack of robust quality control system affecting likelihood of adoption	"These machines are still very primitive. Everyone thinks they're really complicated and they're really advanced, but the technology still is quite young and in many cases the maturity and process stability isn't quite ready because the technology doesn't really have advanced control systems yet." "This is one of the issues with the technology itself, is that additive manufacturing is, in terms of its control systems, still very simple and primitive. And one thing these machines don't do well is monitor the process for quality control."

Another possible factor affecting adoption is that additive manufacturing technology is not currently compatible with the needs of the pharmaceutical sector. Specifically, interviewee's explained that a significant amount of capital is invested in the centralized manufacturing model. Centralized facilities take advantage of global demand volume to manufacture generic and small molecule drugs at a very low cost. Interviewee's argued that due to the sunk capital and the cost advantages of the centralized, model it would be very difficult to make a business case for redistributed technologies such as additive manufacturing.

Several focus group members stressed that a clear need had to first be identified for pharmaceutical firms to be persuaded to adopt the technology. One focus group member suggested the best way to identify the value proposition for additive manufacturing is to start from the patient and work back up the supply chain. Figure 1 suggests the supply of pharmaceuticals can be split into three categories, including advanced therapy medicinal products (ATMP's), small molecule and large molecule/biologics.

Figure 1.0- identifying the value proposition of redistributed manufacturing.



The resounding view of interviewees was that additive manufacturing would not be suitable for the mass production of small molecule and generic pills because of the sunk costs and low production prices of the current centralized model (see Table 4). Instead, additive manufacturing may be more applicable to advanced therapeutics and large molecule drugs because they are more expensive to manufacture and tend to have higher profit margins; thereby justifying the high costs of additive manufacturing machines (see Table 4).

Table 4: Compatibility with needs of adopting organization

Stage	Theme	Code	Quote from Interviewee
Matching Stage	Is innovation compatible with needs of potential adopter	RDM not suitable for small molecule-generic drugs or replacing established production networks	For ATMPs and biologics it might make sense. But for small molecules? I would suggest, forget it. You're not going to get drug manufacturing to be distributed for small molecule products Where it doesn't add value is where you have good distribution networks and you have a product that can get through those distribution networks in a timeframe that meets the patient need but also meets any product restrictions and requirements. We then have to ask ourselves 'okay, so what are the circumstances when that doesn't work so well?' "The cost is probably going to go up, so what's the benefit of having a local plant that can do it? Because you've got regulatory issues, you've got quality issues, What are the practicalities of running a duplicate outfit somewhere else, when you could just make your current facility bigger?"

Several interviewees argued that for additive manufacturing to be adopted a viable application had to first be identified and then trialled by potential adopters. As suggested by Rogers (2003), the easier it is for individuals to see the results of an innovation, the more likely they are to adopt it. It was suggested that a small niche activity should be chosen, one that no commercial company wanted to touch because of scale and complexity (see table 5). Interviewees argued that the ability to demonstrate the technology from research and development through to proof of an integrated development system, would make the case for the technology and increase the likelihood of adoption.

Table 5: Trialability- ability to test innovation prior to adoption

Stage	Theme	Code	Quote from Interviewee
Matching Stage	Trialability – ability to demonstrate innovation	Additive manufacturing needs to trialled before it can be adopted	"I think to get started you need to find little niche that nobody else wants to do because of scale and complexity" "You start with something the big players don't want to be doing anyway, and then you slowly get better at it and eat their lunch in 10 years' time. Actually being able to do it, and show you can do it as an integrated development system, and application, makes the case for the technology"

Table 5 summarizes some of the potential products suited to a redistributed manufacturing approach including gene therapies that are custom tailored to the individual patient. Other potential applications include compound products such as infusion bags that are uniquely tailored to the patient (see Table 6). Pharmaceutical firms are hesitant to develop such products through conventional means as each change in product/packaging interaction requires a stability study making costs prohibitive.

Late-stage dispensing was also suggested as a suitable application for redistributed manufacturing. In the UK, the Pharmaceutical Society has recently permitted decentralised dispensing opening up the possibility of hospital pharmacies using additive manufacturing to produce drug combinations. Additive manufacturing could address the wasteful process currently being used of de-blistering pill packs from the manufacturer. The production of radioactive pharmaceuticals is another potentially viable option which, in effect, already uses a redistributed manufacturing model. In the radio pharmacy model a hospital pharmacists prepares the radioactive injectable on-site allowing it to be administered to a patient in a matter of hours before it dissipates. Additive manufacturing could complement such a model with the product created on-site and administered immediately based on patient need (see Table 6).

Focus group participants felt additive manufacturing could also help the clinical trial process. Currently pharmaceutical firms need to develop a manufacturing screen to reach stage three trials. Once the clinical trial process begins, the sponsor is quite tightly bound to the specific compound that is being tested; changes to the compound itself or even the manufacturing process need to be reported to regulators and could, hypothetically, invalidate study results. Additive manufacturing's ability to produce a variety of compounds, within the confines of a defined manufacturing process, could permit more flexibility during drug development and validation. Finally, it was suggested that redistributed manufacturing technologies would fit humanitarian aid situations where infrastructure is damaged or non-existent. In such a situation bulk active ingredients could be shipped to the point of need and the final product, such as a vaccine, printed as required (see Table 6).

Table 6: Observability- ability to test innovation prior to adoption

Stage	Theme	Code	Quote from Interviewee
Matching Stage	Observability	Additive manufacturing is best suited to customized niche products required on a small scale	"Compounding is an example where, we had some discussion within NHS England when they said 'Actually what we'd really like you to do is just deliver infusion bags ready for patient use. We don't really want our pharmacies to have to do that anymore'. That would be near-to-hospital, near-to-point-of-use, which would be personalised to that individual. That's an unmet need, definitely." "An area closer to distributive manufacturing is late-end dispensary. Redistributed manufacturing in this setting may address a very common practice and a very wasteful one when hospitals de-blister tablets from a manufacturer and use those de-blistered formulations to make new formulations within the hospital. They could just prepare the formulation without having to de-blister and reuse the tablet using

			additive manufacturing, it may solve that problem" "There is one model that's been around for decades called radio pharmacy, for radioactive medicines. So, some of them are treatments, some of them are diagnostics, made at the hospital. You have a mini-manufacturing plant and within 15 minutes, you make the radioactive pharmaceutical injectable, out of an additive manufacturing machine. It's preparing a specific product for a specific patient, at a specific dose, at the time of use."

Conclusion

Despite the rising popularity of redistributed manufacturing technologies in the aerospace and automotive sectors, such a strategy appears to have gained limited traction in the U.K. pharmaceutical industry. The research findings suggest that the industry is largely still at stage two (matching stage) of Rogers (2003) innovation adoption model. While pharmaceutical firms are aware of the problems associated with the centralized manufacturing model, sunk costs and volume advantages make the likelihood of additive manufacturing generic and small molecule drugs highly unlikely. Instead, the findings suggest that redistributed manufacturing technologies are better used to complement existing supply chain configurations. If the basic tenets of Rogers' adoption model hold true then redistributed manufacturing technologies may not be adopted by the pharmaceutical industry until they are viewed a complementary as opposed to replacement innovations.

Theoretical Contribution

Rogers (2003) innovation adoption model states that relative advantage and complexity are the two primary factors that influence the adoption decision. We argue that because redistributed manufacturing technologies complement existing processes there is not a requirement to demonstrate a relative advantage to incumbent technologies. Moreover, we find that it is not complexity, but actually a lack of complexity in terms of quality control processes that is slowing adoption. This paper contributes to theory by identifying that when an innovation is complementary as opposed to disruptive, the key factors influencing adoption will be compatibility, trialability and observability. It was found that for redistributed manufacturing technologies to be adopted, a definite need had to first be identified. Potential adopters should then be given the opportunity to trial the technology and witness the results and benefits. The ability to demonstrate and test the technology on niche products within a redistributed model would likely quicken the pace of industry adoption.

Managerial Contribution

The paper highlights to managers the enablers of and barriers to the adoption of redistributed manufacturing in the pharmaceutical industry. Managers are encouraged to see redistributed manufacturing as a complementary strategy to their current centralized production model. The study highlights to managers some potential applications of RDM including the use of additive manufacturing to create compound products such as infusion bags. Other existing re-distributed models could be further explored such as radio pharmacy where radioactive drugs are created at the hospital for immediate patient use. Late stage dispensing using additive manufacturing technology could cut down on the

waste currently generated from de-blistering. Managers are encouraged to identify other potential applications for RDM within their own supply chains.

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